

CLAIMS

1. A light-stabilized soft capsule formulation comprising:

5 a shell containing a non-water-soluble light-shielding agent and having an average thickness of 200 μm or less; and
a medicament encapsulated by said shell.

10 2. The light-stabilized soft capsule formulation according to claim 1, wherein the amount of the non-water-soluble light-shielding agent is 5 to 30 wt%, based on the total amount of all components constituting the shell.

15 3. The light-stabilized soft capsule formulation according to claim 1 or 2, wherein the non-water-soluble light-shielding agent is titanium oxide.

4. The light-stabilized soft capsule formulation
20 according to any one of claims 1 to 3, wherein the soft capsule formulation has an average capsule size of 2 mm or less.

5. The light-stabilized soft capsule formulation
25 according to any one of claims 1 to 4, wherein the shell is seamless.

6. The light-stabilized soft capsule formulation

according to any one of claims 1 to 5, wherein the medicament is a light-unstable substance.

7. The light-stabilized soft capsule formulation
5 according to any one of claims 1 to 6, wherein the medicament is in a liquid form or the medicament is dissolved or suspended in a liquid base.

8. The light-stabilized soft capsule formulation
10 according to claim 7, wherein the medicament is a vitamin D derivative.

9. The light-stabilized soft capsule formulation
according to any one of claims 1 to 8, wherein the major
15 component of the shell is gelatin.

10. A method for preparing a shell-forming solution which
is used to form a soft capsule shell containing a non-
water-soluble light-shielding agent, said method comprising
20 the step of dispersing the non-water-soluble light-
shielding agent in a medium free from a gelling agent.

11. A method for manufacturing a soft capsule formulation
containing a non-water-soluble light-shielding agent in its
25 shell, comprising:

(i) the step of preparing a shell-forming solution,
comprising the following steps (a) to (c):

(a) dissolving a gelling agent in Medium A;

(b) dispersing the non-water-soluble light-shielding agent in Medium B free from the gelling agent; and

 (c) mixing Medium A containing the gelling agent dissolved therein with Medium B containing the non-water-soluble light-shielding agent dispersed therein; and
5 (ii) the step of forming a capsule shell for the soft capsule formulation using the shell-forming solution prepared in the step (i).

10 12. The method for manufacturing a soft capsule formulation according to claim 11, wherein the step of forming a capsule shell for the soft capsule formulation is accomplished by the in-liquid curing coating method.

15 13. The light-stabilized soft capsule formulation according to any one of claims 1 to 8, which is manufactured by the method according to claim 11 or 12.

14. A unit dose package comprising the light-stabilized
20 soft capsule formulation according to any one of claims 1-9 and 13.

15. A hard capsule, a tablet, an oral solution or an external preparation, which is prepared using the light-
25 stabilized soft capsule formulation according to any one of claims 1-9 and 13.